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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,672	06/17/2002	Gunther Beisel	FI-38PCT	9187
7590 05/06/2004 Friedrich Kueffner Suite 1921 342 Madison Avenue New York, NY 10173			EXAMINER PAGE, THURMAN K	
			ART UNIT 1615	PAPER NUMBER

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/070,672	Applicant(s) BEISEL, GUNTHER	
	Examiner Charesse L. Evans	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Action Summary

Acknowledgement is made of the receipt of applicant's amendment and remarks, filed January 7, 2004.

Acknowledgement is made of the cancellation of claims 1-20 and the addition of new claims 21-38. Claims 21-38 have been withdrawn, as claims 21-38 are to a new invention. Accordingly, claims 1-20 are constructively elected by original presentation.

Response to Arguments

Claims added by amendment following action by the examiner, MPEP § 818.01, §818.02(a), to an invention other than previously claimed, should be treated as indicated by 37 CFR 1.145.

If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144.

Accordingly, newly submitted claims 21-38 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly submitted claims are drawn to a process for preparing and to method claims. As such, processes of preparing and method claims require a different search and analysis.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-38 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

In view of the constructive election by original presentation of claims 1-20 discussion above, the rejection of record of claims 1 and 14-20 under 35 USC 112, second paragraph, is maintained.

The rejection of record of claims 1-20 under 35 USC 103(a) over Beisel (US 6,541,031 B1) is maintained. Beisel teaches a large-volume, sponge-like structure of a carrier material which is loaded with active substances being partly compressed to various shapes (column 2, lines 56-58). The sponge-like structures are foams that consist of gas-filled spherical or polyhedral cells. The carrier material loaded with active substances and ancillary substances is provided with a coating (column 5, lines 65-67). The compositions of the reference are designed for introduction into the

body in the form of capsules, tablets, suppositories or other conventional solid forms (column 6, lines 9-11). The carrier material is composed of semisynthetic or synthetic polymers such as cellulose, ethers, or collagen (column 3, line 46 to column 4, line 2). The material can be compressed without breaking the cell walls to a volume not exceeding $2 - 3 \text{ cm}^3$ (column 3, lines 15-22). Under physiological conditions, the compressed carrier materials should be able to expand its volume by two- to ten-fold, preferably by four- to eight-fold (column 3, lines 36-39). The active substances are all substances with a pharmaceutical or biological action, such as those described in column 4, lines 20-67.

The cited prior art does not expressly teach the pH solubility of the coating compound, however, it is the position of the examiner that this feature does not impart a patentable characteristic. pH solubility is not a patentable feature in that, depending upon the active substance and/or the coating material utilized on the carrier, solubility can be adjusted through routine experimentation. One of ordinary skill in the art would have been motivated to modify the reference with the expectation developing a device of substantial physical mass capable of effectively dislodging matter from the colon walls and creases, thus creating a material which would be effective in cleansing the colon or bowel tract.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 571-272-0593. The examiner can normally be reached on Monday -Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charesse L. Evans
Examiner
Art Unit: 1615

April 19, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600